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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hong Jin

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/724,416	Applicant(s) JIN ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,53,57,69,70,73 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,53,57,69,70,73 and 83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 49, 53, 57, 69, 70, 73, and 83 are pending an under consideration.
2. In the prior action, mailed on October 9, 2007, claims 49, 51-53, 56-58, 61-63, 66-71, 73, 74, 76-78, and 80-83 are pending and rejected.
3. In the Response of March 19, 2008, the Applicant amended claims 53, 69, 70, and 83; and cancelled claims 51, 52, 56, 58, 61-63, 66-68, 71, 74, 76-78, and 80-82.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claims 51-52, 56, 61-63, 66-68, 76-78, and 80-82 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the cancellation of the indicated claims, the objection is withdrawn.
5. **(Prior Objection- Withdrawn)** Claims 53, 69, and 83 were objected to because of the following informalities: it is suggested that the language "to go through only one round of replication" be replaced with the language - - of going through only one round of replication- -. In view of the amendments to the claims, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. **(Prior Rejection- Withdrawn)** Claims 56, 61, 66, 70, 76, and 80 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking sufficient written description support for the claimed general of viruses comprising any recombinant RSV comprising any deletion resulting in an attenuated virus. In view of the cancellation of the rejected claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. **(Prior Rejection- Maintained)** Claims 49, 51, 52, 56-58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 were rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al. (U.S. Patent 5,993,824- of record in the action mailed on June 5, 2002). The rejection is withdrawn

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from cancelled claims 51, 52, 56, 58, 61-63, 66-68, 74, 76-78, and 80-82. The rejection is maintained against pending claims 49, 57, 70, and 73.

The Applicant traverses the rejection of the remaining claims on the basis that support for the claimed invention may be found in the teachings of parent application 08/316439 (U.S. Patent 5,840,520). In support for this assertion, the Applicant points to two portions of the patent. On page 6 of the Response, the Applicant asserts:

The disclosure of a vaccine or an immunogenic composition comprising an attenuated RSV with an NS1 deletion is found in the '520 Patent and entitled to a September 30, 1994 priority date. The invention disclosed in the '520 Patent includes deletions to the RSV genome in order to produce safe and efficacious vaccines (*see, e.g.*, column 44, lines 24-32). The '520 Patent provides by way of example that modifications may be made to influenza, including deletions to the NS 1 and NS2 coding sequences (*see, e.g.*, column 6, lines 51-53). In particular, the '520 patent provides that the principles that are described and illustrated for influenza virus can analogously be applied to other viruses, such as RSV (*see*, column 14, lines 46-55 of the '520 Patent). Thus, the teaching that a virus can be constructed with an NS1 deletion is applicable to RSV.

However, column 6 of the patent does not indicate that the NS1 gene of influenza may be deleted. Rather, the patent indicates that the teachings of the patent "suggest that the nonstructural proteins, NS1 and NS2, are not absolutely required for the replication and express of viral RNP." The patent does not indicate that these proteins were known to be dispensable in influenza, much less in RSV. Moreover, the suggestion in column 14 that the teachings with respect to influenza may be analogously applied to other viruses does not appear as broad as suggested by the Applicant. Rather, the patent indicates that "the principles" described with respect to influenza "may be analogously applied to construct other negative strand RNA virus templates and chimeric viruses," including those based on RSV. The patent does not indicate that each of the specific findings with respect to influenza applies to each of the viruses, but only

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indicates that the general principles described with respect to the construction of influenza RNA templates may be analogously applied.

For these reasons, and because there is no specific guidance in the parent application directing those of ordinary skill in the art to RSV viruses in which the NS1 gene has been deleted, the rejection is maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 49, 51-53, 56-58, 61-63, 66-71, 73, 74, 76-78, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy as applied to claims 49, 51, 52, 56-58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 above, and further in view of the teachings of Knipe et al. (U.S. 7,223,411) and Inglis et al. (U.S. 5,665,362). The rejection is withdrawn from cancelled claims 51-52, 56, 58, 61-63, 66-68, 71, 74, 76-78, and 80-82; and is maintained against pending claims 49, 53, 57, 69, 70, 73, and 83.

The Applicant traverses the rejection of the remaining claims on the same basis asserted with respect to the rejection over Murphy above. For the reasons indicated above, the argument is not found persuasive and the rejection is maintained.

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

13. (New Rejection) A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

14. **(Prior Rejection- Maintained)** Claim 49 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 24 of copending Application No. 11/690,957. No argument is presented in traversal of the rejection. The rejection is therefore maintained.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. **(Prior Rejection- Maintained)** Claims 51, 52, 56-58, 61-63, 66-68, 70, 73, 74, 76-78, and 80-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957. The rejection is withdrawn from cancelled claims 51, 52, 56, 58, 61-63, 66-68, 74, 76-78, and 80-82. No argument is presented in traversal of the rejection. The rejection is therefore maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. **(Prior Rejection- Maintained)** Claims 53, 69, 71, and 83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957 in view of Murphy (*supra*),

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Knipe (*supra.*), and Inglis (*supra.*). The rejection is withdrawn from cancelled claim 71. No argument is presented in traversal of the rejection. The rejection is therefore maintained for the reasons indicated above with respect to the rejection over the Murphy patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claims are allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zachariah Lucas/
Primary Examiner, Art Unit 1648